

Serial No.: 10/532,716
Atty. Docket No.: P70568US0

REMARKS

The Office Action mailed March 18, 2008, has been carefully reviewed and, by this Amendment, Applicant has canceled claim 10, amended claims 1-9 and added claims 11-19. Claims 1-9 and 11-19 are pending in the application. Claims 1, 9 and 14 are independent.

As an initial matter, Applicants have amended the abstract and specification to correct informalities therein noted upon review, including the addition of headings. The text added to page 3 substantially corresponds with the claim text previously referred to but as amended to correspond with the claims as clarified by amendment herein. No new matter has been added. Entry thereof is requested.

The Examiner rejected claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,496,296 to Holmberg in view of U.S. Patent No. 6,764,474 to Nielsen et al. ("Nielsen").

Claims 1 and 9 have been amended herein to clarify the claimed subject matter while retaining the original scope thereof.

As set forth in claim 1, the present invention is directed to an ostomy device having a base plate with an adhesive plate for being fastened on the user, and a collecting bag. The base plate has an opening for receiving an ostomy and a first flange manufactured from a material with a first tensile strength.

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The collecting bag includes a coupling element having a second flange manufactured from a material with a second tensile strength, the first flange being configured for repeated and removable adhesive connection to the coupling element. A flexible layer is placed on an outer surface of the flange having the lower tensile strength, and a layer of adhesive is placed on the outer surface of the flexible layer. The adhesive strength of the adhesive layer provides the adhesive connection between the first flange and the coupling element, with the flexible layer having a yield strength that exceeds the adhesive strength of the adhesive layer. This is not shown or suggested by the prior art.

Holmberg is directed to an ostomy appliance with an adhesive faceplate for attachment to the user, the faceplate 12 having a stoma-receiving opening therein through which the stoma projects. To protect the skin around the stoma from exposure to stomal fluids, a soft sealing material 31 made of a skin-friendly, tacky, hydrocolloid-containing, moisture-absorbing skin barrier material is placed around the stoma-receiving opening to form a fluid-resistant gasket around the stoma, protecting the peristomal skin surfaces (see the abstract). As correctly noted by the Examiner, Holmberg does not disclose a flexible layer between the flange having the lower tensile strength and the layer of adhesive

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that connects the bag coupling element with the base part flange as set forth in claim 1.

Applicant also points out that Holmberg does not teach or suggest that the flange 17 on the collecting bag 11 has a lower tensile strength than the flange ring 27 on the faceplate assembly 12. Instead, Holmberg uses the same language to describe both flange 17 and flange ring 27 as being "relatively stiff" (see column 3, lines 1-5 and lines 36-37, respectively). Accordingly, a person of ordinary skill in the art would have no reason to expect that there would be any difference between the stiffness or tensile strength of these two flanges.

Returning to the absence of teaching in Holmberg on a flexible layer between the flange having the lower tensile strength and the layer of adhesive that connects the bag coupling element with the base part flange, the Examiner cited Nielsen as including such a layer. Like Holmberg, Nielsen also discusses the issue of preventing stomal fluids from contacting the peristomal skin surfaces and, further like Holmberg, discloses a sealing material and fits around the stoma for this purpose. The sealing member in Nielsen is provided as a separate sealing member 5 of hypo-allergenic adhesive that can be in the form of a moldable mass or a ring 20 that fills the void between the stoma and the body side ostomy member (see column 5, lines 16-45; and column 6, lines 48-

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57). Contrary to the Examiner's interpretation, this sealing member 5 in Nielsen is not comparable to the flexible layer of the presently claimed invention.

In relying on Nielsen, the Examiner stated that the "further flexible member 5 comprises an adhesive coated film 8", citing column 5, lines 26-36, "and allows for a more snug and secure attachment of the ostomy bag to the base plate, as disclosed in column 5, lines 60-62". Nielsen does state that the sealing member 5 can include two or more layers 6, 7 covered by a protecting layer or film 8. However, *these layers are not part of the connection between the body side member flange 10 and the coupling element 11 of the collecting bag 4.* Hence, flexible member 5 does not contribute to "a more snug and secure attachment of the ostomy bag to the base plate" (emphasis added). Rather, the flexible sealing member 5 is stated in Nielsen as providing "for a snug automatic sealing *against the stoma*" (column 5, lines 60-62; emphasis added). This snug sealing is aimed at protecting the perimstomal skin surfaces from stomal fluids. The attachment of the ostomy bag to the base plate, on the other hand, is effected by their respective elements, flange 10 and coupling element 11 (see column 5, lines 45-50).

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For at least the foregoing reasons, claim 1 is patentable over the prior art. A person skilled in the art would not look to Holmberg and Nielsen to arrive at the present invention because these patents are directed to an entirely different problem and do not address or provide for a coupling between the body side member and the collecting bag which, when the bag is to be replaced, avoids tearing of flanges and the leaving of residue from the adhesive agent on the body side member as in the presently claimed invention.

Claim 9 is also in condition for allowance for the same reasons as claim 1, being directed particularly to the ostomy collecting bag having a coupling element with a flange manufactured from a material having a tensile strength less than the tensile strength of another flange on the body side member affixed to the user to which the bag is to be coupled. The coupling element flange has a flexible layer on its outer surface, covered by a layer of adhesive that provides the adhesive connection between the coupling element and the body member flange so that said flexible layer is sandwiched between the adhesive layer and the coupling element. Finally, the flexible layer has a yield strength that exceeds the adhesive strength of the adhesive layer. This structure defines over Holmberg and Nielsen for the same reasons just discussed in connection with claim 1.

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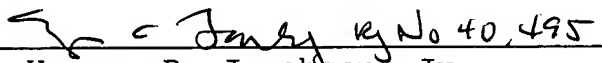
Finally, new claim 14 is also patentable over the prior art for the same reasons as claim 1, differing therefrom by defining the collecting bag flange as being the flange with the lower tensile strength, as in claim 9, and hence stating that the flexible member is on the collecting bag flange between such flange and the adhesive layer.

Favorable consideration and allowance of claims 1, 9 and 14 is therefore requested, along with claims 2-8, 10-13 and 15-19 dependent thereon.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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